

# PSJ3

## Exhibit 271

## **Time Line on OMS Meetings/Discussions with MCK:**

### ➤ **May 5, 2009 - MCK and Purdue - Face to Face OMS Meeting:**

#### **MCK attendees:**

Don Walker Senior VP Distribution Operations  
Robert Pocica Senior VP Chief Security Officer  
Bob James VP Brand RX Pharmaceutical Product Management  
Ina Trugman Assistant General Counsel - Law Department

#### **Purdue Attendees:**

Robin Abrams, V.P. Associate General Counsel  
Mark Geraci, V.P. Chief Security Officer  
Jack Crowley, Executive Director, CSA Compliance  
Steve Seid, Executive Director, National Accounts  
Luis Bauza, Director of Investigations

#### **Summary of Discussions:**

**Robin spoke of Purdue's interests** – FFS data; Purdue OMS metrics; beneficial for both; other information (sales force; DEA actions, etc) - no desire to create supply interruptions or thwart legitimate patient access.

**Don Walker stated that McKesson** was in 100% agreement with Purdue and he recognized that this collaborative effort was the right thing to do. He stated that he employed six (6) Directors of Regulatory Affairs around the country and that there were 5/6 Distribution Centers.

Don spoke about the "2005 debacle" (DEA action against MCK) and how MCK had invested \$ millions in their Suspicious Order Monitoring Program. Basically, McKesson makes every effort to understand the pharmacy account and then they establish a threshold for ordering. It's Don's job to build relations with DEA Field Diversion Program managers (DPMs) and Group Supervisors - as well as his DRAs.

### ➤ **March 9, 2010 – MCK and Purdue OMS Meeting (limited audience):**

#### **MCK attendees:**

Bill Mahoney, Director Regulatory Affairs South Region  
Dave Gustin, Director Regulatory Affairs North Region

#### **Purdue Attendees:**

Jack Crowley, Executive Director CSA Compliance

### **Summary of Discussions:**

Purpose of the Meeting: to further the cooperation between MCK and Purdue and to develop coordinated protocols for communication in the identification of patterns of interest.

Discussed Purdue's Order Monitoring System (OMS), MCK Control Substance Monitoring Program (CSMP) and highlights of recent DEA directives and interpretations which included:

- It is not DEA's intent to negatively impact those pharmacies filling prescriptions for legitimate medical purposes.
- **Prevent Diversion - onus squarely on the registrant**
- Exercise due diligence to avoid filling suspicious orders
- Exercise due care in confirming the legitimacy of all orders prior to filling.
- Must conduct an **independent analysis of suspicious orders prior to completing a sale** to determine whether the controlled substances are likely to be diverted from legitimate channels. The supplier must comply with the CSA and implementing regulations.
- Know your customers - don't rely on **rigid formulas**
- **(Do not) fill these (suspicious) orders without first determining that order is not being diverted into other than legitimate medical, scientific, and industrial channels**
- **Failure to maintain effective controls against diversion is inconsistent with the public interest** as that term is used in 21 USC 823 and 824, and may result in the revocation of the registrant's DEA Certificate of Registration.

### ➤ **March 6, 2012 – MCK and Purdue Face to Face OMS Meeting**

#### **MCK attendees:**

Don Walker Senior VP Distribution Operations  
Bill Mahoney, Director Regulatory Affairs South Region  
Tom McDonald, Director Regulatory Affairs Western Region  
Michael Oriente, Director Regulatory Affairs Northern Region  
David Gustin, Director Regulatory Affairs Midwestern Region  
Gary Hilliard, Directory Regulatory Affairs Supply Solutions  
Tracey Jonas, Director Regulatory Processes

#### **Purdue Attendees:**

Robin Abrams, V.P. Associate General Counsel  
Mark Geraci, V.P. Chief Security Officer  
Jack Crowley, Executive Director, CSA Compliance  
Steve Seid, Executive Director, National Accounts  
Luis Bauza, Director of Investigations

**Summary of Discussions:**

- Discussions regarding the team the MCK created in 2008, the new system solution MCK was using and the feedback received from local DEA Offices.
- Changes made because of FL Pill mill law where a cap was established per customer.
- Progressing the right way in evaluating accounts but MCK was not sure if they were doing enough.
- Discussion regarding the collaboration efforts with Purdue and the successful information sharing regarding accounts.
- Identifying hot Spots and the due diligence work done on accounts including the evaluation of % of cash versus non-cash prescriptions filled.

➤ **July 11, 2013 – MCK and Purdue OMS Conference Call**

**MCK Representative:**

Don Walker Senior VP Distribution Operations

**Purdue Representatives:**

Robin Abrams, V.P. Associate General Counsel  
Giselle Issa, Director, OMS and Records Management

**Summary of Discussions:**

Topic of discussion was mainly obtaining an understanding of the significant changes in MCK's order monitoring process that led to the suspension of 65 accounts until further review and evaluation as to whether MCK will continue to service the accounts.

MCK explained their rationale behind the suspension. They had opted to change their account evaluation model from a subjective model to a more objective data driven evaluation.

MCK also embarked on an aggressive campaign focused on training and reminding pharmacist on their corresponding responsibilities.

A number of accounts were discussed and MCK decision was shared as to the action taken against such accounts. Robin also discussed the importance of looking at the data to identify outliers keeping in mind Patient with legitimate need having access issues to their medication. She also shared some of the different processes used by other industry members in their evaluation of their accounts. Walker stated that it is an interesting area worth discussing further with MCK internal management and counsel.

➤ **May 5, 2014 - MCK and Purdue - Face to Face OMS Meeting:**

**MCK attendees:**

Don Walker, SVP Distribution Operations

Krista Peck, SVP for Regulatory Affairs & Compliance (prior position: 10 years Attorney at MCK)

Gary Boggs, Senior Director of Regulatory Affairs (prior position: 27 years at DEA)

Lisa Young, Senior Director of Regulatory Affairs (prior position: 25 years at DEA)

Christine Menendez, Staff Attorney & CS (prior position: DEA Chief Counsel)

Nate Hartle, Sr. Dir. of Regulatory Affairs (prior position: 19 years Corporate Security at Target)

**Purdue Attendees:**

Robin Abrams, V.P. Associate General Counsel

Mark Geraci, V.P. Chief Security Officer

Steve Seid, Exec Dir., National Accts/Trade Relations

Giselle Issa, Dir., Order Monitoring System & RM

John Gilbride, Dir., CSA Compliance & LELE Program

**Main Points of Discussion:**

- There has been a significant review and revision of the Controlled substance program which resulted in establishing a separate group encompassing control substance and regulatory affair that group to be headed by Krista Peck by July of 2014.
- Order Monitoring group which is now part of the regulatory compliance group has been expanded in the last 2 years from 6 to 32.
- Main function of the new group is to perform a detailed review of controlled substance monitoring program in response to increased activities by DEA starting November of 2012.
- The first step was to engage Quarles and Brady to provide legal advice in dealing with DEA inquiries which has covered a cyclical review of 16 out of 30 distribution centers.
- The controlled substance order monitoring program was enhanced to include strong statistical methods in establishing thresholds to accommodate pharmacy size, geographical norms, answers to questionnaires received from pharmacies and other factors.
- Program's evaluation is a work in progress especially with the expansion of the group from 6 individuals to 32 and bringing in ex DEA members internally to help set up a more comprehensive order monitoring program.
- Based on the DEA cyclical review of the 16 distribution centers a number of observation were made on what DEA was concentrating on such as:
  - Comparing MCK data to the data reported in the ARCOS system by customers (Retail chains, hospitals, independents).
  - Review MCK program with the Chains
  - Review interactions with the Chains

- Reports of suspicious order to the DEA
- In response to the observations made of DEA inquiries the following changes were made:
  - Reviewed and adjusted thresholds
  - Enhanced education training of pharmacies to recognize abuse and diversion of product which includes material pulled from DEA conferences and web training information from ONDCP and other training material. Don Walker commented that it was appalling how little some of the independent pharmacies knew about abuse and diversion and their obligation on identifying orders of concern.
  - Identify better statistical outliers and statistical analysis
  - Share the same educational material to chains as well as retailers
  - Share material that MCK usually covers in their trade shows
- Don Walker stated that MCK especially in the last 18 months is looking for better ways to collaborate and take opportunity to work together in educating pharmacies and chains against abuse and diversion. Don stated that MCK is not promising a good seal of approval of the programs in place but they are promising to maintain a strong regulatory environment. With regard to all the actions the DEA took against wholesalers and chains, Don stated that he is seeing that the concentration today is moving away from why is this happening to me to how can we prevent it from happening.
- The area that spiked questions and discussions was the section regarding patient access.
- One of the points that was brought up was that because of the current reduction in thresholds, sometimes the allotted amount is chewed by the patients who have oxycodone IR 30 and so by the time the patients with the OxyContin scripts come in to fill their prescription are told that they no longer have any inventory to fill their prescription.
  - Don Walker stated that it is the pharmacies has a decision to make as to how to manage their inventory and so they are educating them to recognize abuse and diversion and they are leaving it up to them to manage their thresholds. He believes the pharmacy is better equipped in managing their thresholds since they are familiar with their customers.
  - Don stated that the noise from having access to the medication has gone way down since MCK has been clear and specific in the way they are managing their thresholds and he believes that some of the pharmacies are doing a better job too in managing their inventory.
  - Don said there is a significant effort on MCK's part on establishing the appropriate thresholds. They have carved out the oxycodone IR 30mg and reduced their portion with regard to the total oxycodone threshold.

- When Don was asked about the reduction of the thresholds across all oxycodone he responded that they did not reduce it across all. He said that if the total RX business went up and CS % of the business marginally went up too, the thresholds were increased. The opposite happened when the CS % kept going up while the total RX did not increase then thresholds were reduced.
- Don has said that the new team is looking at evaluating the order monitoring program and they will continue to look for opportunities to evolve the program.
- With regard to advice for independent pharmacies, Don stated that:
  - What the independent pharmacies need to do is to look at their own data. Review the aggregate numbers as to what is a normal retail pharmacy according to DEA which MCK is using as a guide.
  - Look at prescriber's data and identify the highest prescribers. Prescribers and total number of orders are most important. MCK shares with the independents the numbers and tells them what they see as outliers and sometimes they are surprised to find that out.
  - Need to make sure they tell their patients to bring all their prescription not just the pain medicines so they have a proper history of the type of patients they are getting.
  - Look at trending by product and stay focused on reviewing prescribers' data.
- Don added that he wishes there was a way for all the wholesalers to get conformity in the way to identify outliers to try to control the risk of abuse and diversion. He also stated that collaboration with the manufacturers is also important since we are all battling the same issues.
- Giselle shared with MCK that one of things that other wholesalers are currently doing is adding oxycodone IR 15mg to the 30mg in their carve outs based on observations made that since DEA has squeezed the balloon on the 30mg some wholesalers have observed movements to the 15mg. Don seemed very appreciative of the information being shared and stated that these are the type of collaboration they are looking for.
- Don concluded by saying that Krista's team is in the process of evaluating the best way to have future contacts with the manufacturers and they will inform us as to who our contact will be in the future. In the mean time we will keep contacting the field directors until we hear further.

All in all this was a positive and informative meeting where the Purdue team was introduced to the new MCK team of the revamped regulatory affairs and compliance program.

### **Current Activities with MCK and Some of its Chain Pharmacies**

Giselle has quarterly calls with MCK's contact person Gary Boggs, Senior Director of Regulatory Affairs to share trends and other relevant public material related to pharmacies and physicians.

Additional contact with Gary is made when accounts are identified for review because they met Purdue's Algorithm.

Giselle has also established OMS collaboration calls with some of the Chain Pharmacies that are serviced by MCK such as:

**Albertsons** – OMS onsite visit in August 2015 and ongoing quarterly collaboration calls

**Ahold** – OMS conference call and semiannual collaboration calls going forward

**Bi Lo Holdings** – OMS conference call a couple of years ago and quarterly collaboration calls

**HEB Grocery** – OMS conference call and semiannual collaboration calls going forward